

II: DRUG REGULATION IN INDIA

1. Overview

The bulk of drug regulation in India is based on the centrally-enacted Drugs and Cosmetics Act, 1940 (DC Act) and the corresponding Drugs and Cosmetics Rules, 1945 (DC Rules). However, because 'public health' is a state subject under the Indian constitutional scheme, state governments also exercise considerable control over drug regulation within the country. Consequently, this has contributed to an absence of a clear and codified distribution of powers and responsibilities between the centre and the states. This lack of an authoritative regulatory body is the common cause underlying multiple problems that plague drug regulation in India. The next sub-section maps the jurisdictional division between the centre and the states. The various central and state authorities suffer from the administrative vice of shortage of personnel, lack of planned funding and an absence of efficient regulation. While sub-section 3 identifies the issues with the procedure adopted by the drug regulatory agencies, sub-section 4 discusses the problems arising from the broken organizational structures within the drug regulatory agencies. Sub-section 5 delves into the cracks in the infrastructure sustaining drug regulation in the country. Sub-section 6 attempts an evaluation of the performance of the drug regulatory bodies between 2015 and 2019, and sub-section 7 briefly discusses budget and financial administration in matters of drug regulation.

2. Jurisdiction and administration

The DC Act grants the central government with the power to regulate import, manufacture and sale of drugs and cosmetics including but not limited to defining misbranded, adulterated, spurious and other standards of quality and making rules for their regulation. The central government is also given the power to restrict or regulate the import, manufacture, sale and distribution of drugs in public interest and direct state governments as necessary. state governments, on the other hand, are given the power to implement the DC Act and any rules made under the Act. Provisions dealing with the appointment, powers and duties of Government Analysts

(for the drug testing laboratories) and Drug Inspectors (for the drug control administration), as well as licensing, storage, sale, display, inspections, confiscations are further detailed in the DC Rules.

On the regulatory front, the Central Drugs Standard Control Organization (CDSCO), headed by the Drug Controller General of India (DCGI) is primarily responsible for coordinating the activities of the SDRAs, formulating policies, and ensuring uniform implementation of the DC Act throughout India. The DCGI is responsible for handling matters of product approval and approval standards, clinical trials, introduction of new drugs, and import licenses for new drugs. A drug may be licensed for manufacturing in a state only once it has been approved by CDSCO.

Bans on drugs issued by CDSCO, although rare, are also authoritatively binding on the SDRAs. According to the Minister of Health and Family Welfare, between 2013-2015, only three drugs were banned citing risk to human beings and availability of safer alternatives in the country.⁵

Chapter II of the DC Act constitutes three agencies for assisting and advising the central and state governments. The Drugs Technical Advisory Board (DTAB) advises the governments on technical matters arising out of drug control administration. The Drugs Consultative Committee (DCC) advises the governments and the DTAB on matters tending to secure uniformity in drug control administration throughout the country. The Central Drugs Laboratory (CDL) functions as the central drug testing laboratory for CDSCO. While the DTAB includes two central government nominees from among persons in charge of drug control in the states, it is the DCC that is the larger representative body, having representatives from all the states in the country. Suggestions and recommendations originating at the DCC go through the DTAB and become executive guidelines or rules, if they are approved by CDSCO.

State Drug Regulatory Authorities (SDRAs) established under the DC Act are responsible for licensing of manufacturing establishments and sale premises,

⁵ Lok Sabha Unstarred Question No. 1042, answered by the Minister of Health and Family Welfare on 4 December 2015

undertaking inspections of such premises to ensure compliance with license conditions, drawing samples for testing and monitoring of quality of drugs, taking actions like suspension/cancellation of licenses, surveillance over sale of spurious and adulterated drugs, instituting legal prosecution when required, and monitoring of objectionable advertisements for drugs.



Figure 1: Division of responsibilities between CDSCO and SDRAs

Source: DC Act and Rules; CDSCO/SDRA websites; author compilation

The State Drug Controller (SDC) heads the SDRAs and reports to a joint secretary in the health department of the state government. A typical SDRAs has Drug Inspectors reporting to the Deputy Drugs Controller who also acts as the Licensing Authority for the state. Administrative matters such as departmental budgeting, appointments, training of officers, and allotment of funds and resources for inspections, falls under the jurisdiction of the state governments. This report found that a number of SDRAs were conjoined with the food regulatory departments (FDAs) of the state, making it difficult to clearly demarcate the available funds and resources between the two. For example, in Himachal Pradesh and Jammu & Kashmir, budgets are allotted to the state FDA (Food and Drug Administration) as a whole. Similarly, the Jammu & Kashmir state laboratory is used for both food and drug testing. The problems of porous administration are aggravated by complaints

that have surfaced⁶ that claim that the already overworked Drug Inspectors are often given non-drug regulatory responsibilities. It must also be noted that unlike the DTAB and DCC that complement the workings of CDSCO, there is no provision for state-level advisory committees that can audit or bridge the gap between resource allocation and workload of the departments. This results in the Drug Controller being required to manage with the available budget to undertake multiple responsibilities for both food and pharmaceutical regulation. There appears to be no scope for direct feedback from the executive on budgetary allocations to the departments commensurate with the work they undertake. The administration of SDRAs is riddled with lack of communication between the executive implementing the law, and the central and state authorities responsible for policy making and resource allocation.

3. Process of drug regulation

The DC Act entrusts CDSCO with the responsibility for the approval of new drugs, and the conduct of clinical trials in the country, as well as laying down the standards for drugs, controlling the quality of imported drugs, oversight over the SDRAs, and an advisory role in ensuring uniformity in the enforcement of the DC Act itself.

CDSCO approves new drugs based on a combination of non-clinical data, clinical trial data (focusing on safety and efficacy) from abroad as well as in India, and the regulatory status of the drug in other countries.⁷ The law around new drug approvals is contained in Rules 122 A, 122 B, 122D, 122 DA, 122 DAA, 122 DAB, 122 DAC, 122 DB, 122 DD and 122 E of Schedule-Y of the DC Rules. The law permits a waiver of requiring local clinical trials if the Licensing Authority decides it is in the public interest to grant permission to import / manufacture the new drug on the basis of data available from other countries. In special circumstances, such as drugs

⁶ See, for example, Chowdhury, N, et al (2015), "Administrative Structure and Functions of Drug Regulatory Authorities in India," ICRIER, Working Paper 309, September, available at: https://icrier.org/pdf/Working_Paper_309.pdf, last accessed: 2 February 2019; Chokshi, M, et al (2015), "Drug Quality and Safety Issues in India," ICRIER, Working Paper 310, September, available at: https://icrier.org/pdf/Working_Paper_310.pdf, last accessed: 2 February 2019

⁷ Lok Sabha Unstarred Question No. 1393, answered by the Minister of Health and Family Welfare on 18 July 2014

required in life threatening / serious diseases or diseases of special relevance to the Indian health scenario, the law permits the Licensing Authority to abbreviate, defer or omit clinical data requirements altogether.

Applications for approval of New Drugs are evaluated by the 12 Subject Expert Committee (SEC) (formerly referred to as New Drug Advisory Committees (NDAC)), consisting of experts usually drawn from Government Medical Colleges and Institutes across India. The approval or otherwise is granted based on the recommendations of these committees.

The drug approval process in practice has had its fair share of criticism, notably in the 2016 ban by the central government on fixed dose combinations (FDCs), with the government overruling prior approvals given by the DCGI and state licensing authorities, and without seeking advice from DCC and DTAB. According to critics of the ban, mainly from amongst pharmaceutical companies, there was a blatant flouting of the rule of law in the announcement of the ban. They said that besides due process, principles of natural justice were also ignored, with manufacturers not being given a chance to be heard, and reasoned orders not being given. The government has defended itself against the allegations, but is already facing litigious challenges in several states from several multiple pharmaceutical companies.⁸ Overall, this has put considerable cloud over the new drugs approval and regulatory process in India, and with the ban being issued by the government rather than by CDSCO, this particularly casts a shadow on the legitimacy of CDSCO as a regulatory body.

Besides approval, the other important regulatory roles are regarding licensing and inspections. Sections 22 and 23 of the DC Act give the Drug Inspectors (DI) the power to inspect premises manufacturing or selling drugs or cosmetics and take samples of any drug or cosmetic in exchange of its fair price and a written acknowledgement. Where the sample has been taken for testing or analysis, the DI must inform about its purpose in writing to the owner of the premises. The provisions also direct the DI to divide the samples into four (three, if taken from the

⁸ Lok Sabha Unstarred Question No. 82, answered by the Minister of Health and Family Welfare on 29 April 2016

manufacturer) properly sealed portions or take as many units of the drug. The Government Analyst under Section 25 of the DC Act must then prepare a signed report which is then taken to be a conclusive fact upon the standard of quality of the drug. These provisions are complemented by the DC Rules which elaborate on the duties of the Government Analyst, the Drug Inspector and the Licensing Authority.

In 2017, the DC Rules were amended, making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drug Inspectors of both the central government and the concerned state government. The amendment also made a similar joint inspection mandatory for manufacturing premises for not less than once every three years or as needed per the risk-based approach. Recently, the DTAB has recommended amending the DC Act to authorize Licensing Authorities to issue stop-sale orders for drug retailers. Earlier, this power to issue stop-sale orders was available to the Licensing Authorities in cases of manufacturing non-compliances only.⁹

⁹ DTAB meeting on 2 April 2019, Agenda No. 12.

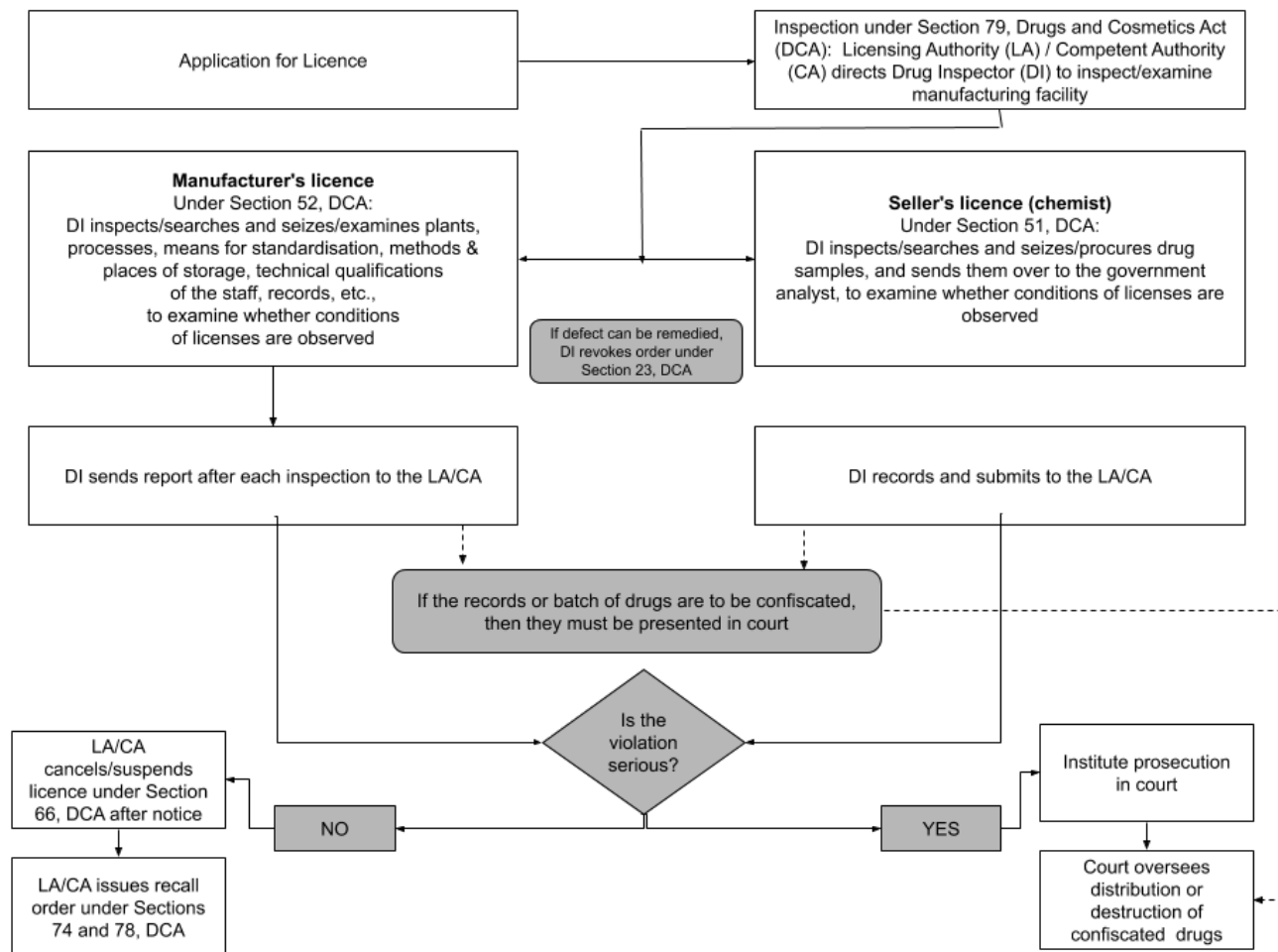


Figure 2: Stages of regulation in drug inspection

Source: DC Act and Rules; author compilation

The central government's in-house policy thinktank, NITI Ayog, proposed a number of changes in the approval process in the pharmaceutical and medical research sector with the objective to boost innovation. In order to streamline, update and simplify the process, it was suggested that there be a single window system for approval, a time limit of 30 days for approval/rejection from the date of application, and review of other age-old procedures encourage innovation in India.¹⁰ So far, states have taken concrete steps towards introducing a single window clearing system and a time limit for approval. The DTAB was of the view that drugs should be handled only by registered trained pharmacists who are aware of good storage and

¹⁰ Lok Sabha Unstarred Question No. 5535 by the Minister of State in the Ministry of Health and Family Welfare on 7th April, 2017.

distribution practices.¹¹ The DTAB has recommended including Graduate in Pharmacy/Pharm.D as one of the qualifications for technical staff supervising the manufacturing and testing of drugs.¹² The DCC also recommended a cadre overhaul and introduction of drug testing laboratories in 2019.¹³ In a response to a starred question in the Lok Sabha,¹⁴ the Minister of Health and Family Welfare listed the measures instituted by the government to strengthen drug regulation across India. The answer listed introducing stringent penalties including making certain offences cognizable and non-bailable, establishment of special designated courts for the trial of offences under the DC Act for speedy disposal of cases, announcement of a Whistle-Blower Scheme, and starting risk-based inspections of manufacturing facilities. As per the information provided, 22 states have set up special designated courts.¹⁵

New labelling norms have been proposed to trace the origin and movement of Active Pharmaceutical Ingredient (API) from manufacturers to formulators through a system of networking. The DTAB recommended amending the DC Act so as to make QR coding mandatory on labels of APIs.¹⁶ The DTAB also went into a detailed discussion on the merits of the “Track and Trace system” which would allow consumers to authenticate the genuineness of the drug. A portal for Indian drug authentication track and trace, DAVA – Drugs Authentication and Verification Application, was also presented,¹⁷ but its implementation is still in initial stages.¹⁸

Amendments to the DC Rules in 2017 have also introduced perpetual licenses for drugs, whereby the manufacturing and sale licences of drugs will remain valid if the licensee deposits a licence retention fee every five years, unless the licences are suspended or cancelled by the Licensing Authority. For manufacturing licences, the premises will be inspected jointly by the central and state Drugs Inspectors at least

¹¹ DTAB meeting held on 18 August 2015, Agenda No. 3.

¹² DTAB meeting held on 2 April 2019, Agenda No. 15.

¹³ DCC Meeting 20 February 2019, Agenda No. 7

¹⁴ Lok Sabha Starred Question no 54 answered by the Minister of Health and Family Welfare on 18th November 2016. [check for an earlier answer]

¹⁵ Lok Sabha Unstarred Question No. 4692 by the Minister of State in the Ministry of Health and Family Welfare on 23rd March 2018.

¹⁶ DTAB meeting on 2 April 2019, Agenda No. 4.

¹⁷ DTAB meeting on 22 April 2015, Agenda No. 1

¹⁸ See website, <http://dava.gov.in/>

once in three years, or as required as per the risk based approach. These perpetual licenses have been introduced to do away with the requirement of periodically renewing manufacturing and sale licences, with a view to ease the continuation of business. However, the implementation of this is yet to be tested.

The following paragraphs discuss the problems that appear to have remained in the regulatory process despite statutory and governmental efforts to make amendments.

A. Problem Identified: Information Asymmetry

Causes: No Time Frame, No Centralised Record Keeping

Even with the detailed nature of the directions under the DC Rules, the provisions fail to mention a time frame within which each stage of regulation must be completed. This further feeds into the lag in communication between administration, policy makers and the officers implementing the provisions.

As part of attempts at reforming drug regulation in the country, the SDRAs committed to a publicly notified time limit listed variously as the citizen's charter or client's charter. It lists the services provided by the department along with the maximum response time. The time period begins from the day all documents have been submitted. However, a critical concern is that the states do not have a time frame within which they must complete the inspection of facilities. Thus, the discretion available to the Licensing Authority, for example, not only makes them choose the punishment for the offender in the absence of their offence record but also allows for the administrative/punitive action to be delayed, as there is no time limit within which an inspection must be concluded. The state of Mizoram stands out partly on this account as it specifies that all seized material as well as the accused be produced before the Session Judge/1st Class Magistrate within 24 hours, but it fails to extend time limits to other parts of the process.

State	Grant of Manufacturing Licenses	Renewal of Manufacturing Licenses	Grant of Sale Licenses	Renewal of Sale Licenses
Andhra Pradesh	60	60	30	60
Assam	45-60, depending on the type of drug/cosmetic	No limit applicable	45	No limit applicable
Delhi	75	Not provided	35	Not provided
Goa	30	Not provided	30	Not provided
Gujarat	60	60	30	30
Himachal Pradesh	21	21	21	21
Jharkhand	90	90-120, depending on the type of drug/cosmetic	30	30
Kerala	28	Not provided	30	30
Karnataka	60	60	30	30
Maharashtra	30	Not provided	30	Not provided
Mizoram	60	Not provided	30	Not provided
Rajasthan	90	Not provided	20	Not provided
Telangana	14	Not provided	14	Not provided
West Bengal	90	90	90	90

Table 1: Response time for grant and renewal of sale and manufacturing licenses

Source: Various state government websites; author compilation

Further, data from responses to our RTI applications shows that the number of prosecutions launched is minute compared with the number of failed compliances. (For example, while Mizoram reported 4 for 141 failed compliances, Odisha reported 6 for 876 and Jharkhand reported 7 for 1723 failed compliances. An analysis of prosecution data follows in another section of this report). Launching a prosecution is only one of the many options available to the Licensing Authority; others include issuing recall orders or banning licenses. Therefore, the number of prosecutions launched with respect to failed compliances will not reveal the full picture of regulatory action taken in such cases. Whether a firm should be prosecuted depends

upon the type of offence as well as whether the entity involved is a repeat offender or not. For the rules on guiding the discretion available to the SDRAs to work properly, there needs to be updated information for the Licensing Authority on manufacturer/seller. The states, however, do not maintain a track record of the history of departmental actions taken against a manufacturer or a seller. It, thus, becomes difficult to mete out appropriate and proportionate punishments.

Adding to the limited information available, replies to our RTI applications show that once an inspection report is submitted, in most cases, the Drug Inspector is not informed about the action taken subsequently. Public information officers from districts in Jharkhand and Odisha, for example, have claimed that the district drug administration office does not have information on actions taken on inspections failing compliance. In the absence of this follow up information, risk-based inspections lose their teeth. Further, in order to spread awareness on a real time basis regarding drugs which are not of standard quality, the CDSCO publishes drug safety alerts on monthly basis on its website. The monthly publication of drug safety alerts includes a list of drugs which are declared as 'Not of Standard Quality, spurious, adulterated or misbranded' along with the details of batch number and manufacturing site. The list also mentions the details of testing laboratories which perform the quality test of drug along with the reason of failing the test for the particular drug. While this system solves the problem of *post facto* communication, it fails to provide any significant input to the Licensing Authority in determining appropriate liability of the violator. It must be noted that the XLN software aims to solve the problem by creating information nodes linking automatic delivery of recall notices through mobile-based messaging services to drug distributors and sellers in the state. The efficiency and success so far of the system is hard to evaluate for lack of information.

To deal with the problem of non-uniformity in the interpretation of the provisions of the law and their implementation, lack of adequate infrastructure and varying level of the competence of regulatory officials resulting in inadequate enforcement, a risk-based inspection system was introduced. Under the system, a checklist and evaluation tool for conducting and reporting the inspections was prepared and shared with all the stakeholders. Central and state Drug Inspectors and Government

Analysts were trained. An inspection team comprising an Additional Drug Controller, one Drugs Inspector of the state and CDSCO, one Assistant Drugs Inspector and one Government Analyst were expected to conduct inspections and share the inspection report with the concerned manufacturers and respective state Drugs Controllers for taking appropriate actions. The DCC recommended extending the training and subsequently, the risk-based inspection system, to state-level Drugs Controllers. However, as per a more recent assessment, the risk-based inspection has not started yielding results. While compliances range between 0 to 0.071%, more than 90% inspections have been found to be non-compliant.¹⁹

The DTAB recommended amending the DC Rules so as to include mandatory submission of data by licensed manufacturing units and medical products on SUGAM, which is the online portal maintained by CDSCO. The self-declared data is then to be verified by the concerned state Licensing Authorities.²⁰ However, no such amendment has been made to the legal framework. In the absence of concerted effort, the absence of record-keeping mapped across licensees and non-compliances creates an information gap which has contributed to the inefficiency in regulation.

B. Problem Identified: Uneven Implementation Of Penalties

Causes: Lack Of Clear Definitions, Non-Implementation Of Guidelines Directing Discretion

While much of the drug regulation process has been codified, the officers are bestowed with wide discretion at two major junctures in the regulatory process. Firstly, a Drug Inspector may revoke the order issued under Section 23 upon being satisfied that the defect in the drug/cosmetic can be and has been remedied. Secondly, once a Drug Inspector has submitted the inspection report to the Licensing Authority, the Licensing Authority decides whether the violation is serious enough to warrant prosecution. The Licensing Authority may choose between suspension of the license, revocation of the license and prosecution of the licensee. However, neither the DC Act nor the DC Rules provide any metrics to guide this

¹⁹ DCC meeting of 4 and 5 November 2016

²⁰ DTAB meeting on 16 May 2018, Agenda No. 3.

discretion. This has resulted in an uneven implementation of penalties where a repeat offender may get away with suspensions in one state but might be prosecuted in another. A study shows that the identification of a drug as spurious or NSQ (not of standard quality) depends on the Drug Inspector's reading of Form 13.²¹ This points to the potential of uneven implementation even within states.

Conversely, the absence of clear definitions and standards in the DC Act have also caused harsh punishments for violations lacking criminal intent. In May 2018, the Small and Medium Pharma Manufacturers Association (SMPMA) demanded the implementation of the DCC guidelines for taking action on spurious or NSQ drug samples in light of enhanced penalties under the DC (Amendment) Act of 2008.²² It was highlighted that the absence of a clear definition of NSQ in the legal framework leads to the same punishment being meted out for spurious, adulterated drugs, as well as for drugs that are merely defective. They argued that issues like decreased potency, disintegration, etc. should not be treated at par with adulterated or spurious drugs.

To deal with the problem of uneven penalties for violations across states, CDSCO released "Guidelines For Taking Action On Samples Of Drugs Declared Spurious Or Not Of Standard Quality In The Light Of Enhanced Penalties Under The Drugs And Cosmetics (Amendment) Act, 2008". Among other things, the guidelines attempt to harmonize the system of penalties with the degree of offence introducing parameters such as criminal intent and sufficiency of administrative action for judging the seriousness of the offence. However, in the absence of regular trainings, the implementation of these guidelines is stuck in limbo.

²¹Chokshi, M, et al (2015), "Drug Quality and Safety Issues in India," ICRIER, Working Paper 310, September, available at; https://icrier.org/pdf/Working_Paper_310.pdf, last accessed: 2 February 2019

²²Yadav, L (2018), "SMPMA urges DCGI to act against NSQ drug manufacturers as per DCC guidelines", 17 May, *Pharmabiz*, available at: <http://www.pharmabiz.com/NewsDetails.aspx?aid=108929&sid=1>, last accessed 10 July 2019

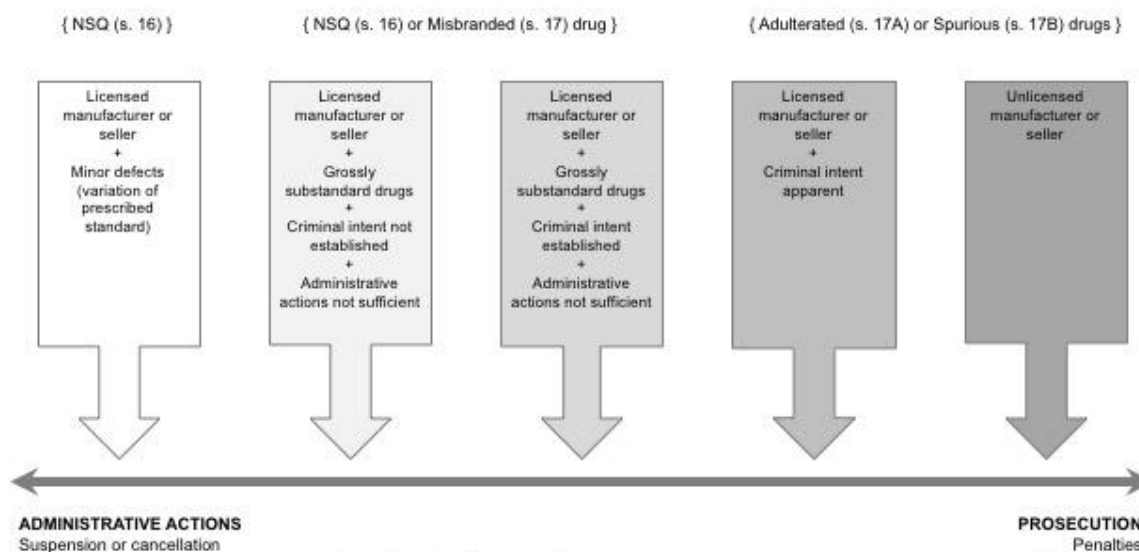


Figure 3: Discretion in drug regulation

Source: CDSCO Guidelines on penalties, 2008; author compilation

SMPMA was in favour of the state screening committee proposed under the DCC Guideline on grounds that this process would safeguard the interests of genuine manufacturers. They also demanded that the accused be provided with the investigation report as well as the test report issued by the Government Analyst, and that the report should contain the complete testing protocol along with the raw and factual data so that they may be better equipped to defend themselves. To deal with the problem of uneven implementation, the DTAB agreed to various recommendations such as minimum experience for Licensing Authorities, creation of Intelligence cells in each state, deputation of state regulatory officials to the central regulatory system and vice-versa, cadre restructuring in Drugs Controlling Authorities etc.²³ However, concrete implementable steps are yet to be taken by CDSCO or the Ministry of Health and Family Welfare. In a recent meeting of the DTAB, it was acknowledged that despite the Guidelines, the implementation was non-uniform across states. It was recommended that the Guidelines be standardized and incorporated into the DC Rules.²⁴

²³ DTAB meeting on 16 June 2017.

²⁴ DTAB meeting 29 November 2018, Agenda no 2.

4. Organisational structure

The DC Act and DC Rules create the posts of Drugs Inspectors and Government Analysts within the central and state drug administration. Besides laying down the duties and procedure to be followed in discharging these duties, the Act and Rules also provide the eligibility standards for two of the most important positions in drug regulation.

In a response to a starred question in the Lok Sabha,²⁵ the Minister of Health and Family Welfare listed conducting workshops and training programs for skill enhancement as a measure undertaken to strengthen drug regulation. The government identified areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practices (GCP) and Good Storage and Distribution Practices (GSP) for training regulators and industry personnel. This was to be done in partnership with other departments, industries and regulators of other countries including USA and European Union.

The following paragraphs discuss the problems that have emerged in our study of the organisational structure of drug regulation in India.

A. Problem Identified: Overworked Administration

Causes: Low Sanctioned Strength And High Vacant Posts

The DC Act and DC Rules mandate the inspection of all retailers and manufacturers at least once a year. In 2003, the Mashelkar Committee identified a lack of trained personnel as one of the major issues in Indian drug regulation. The recommendations fixing a formula for adjudging the required number of Drug Inspectors in a state were reiterated in the 59th Parliamentary Committee Report of 2013. According to the formula, there needs to be one drug inspector for every 50 manufacturing units and one for every 200 sale/distribution retailers. In a Lok Sabha

²⁵ Lok Sabha Starred Question no 54 answered by the Minister of Health and Family Welfare on 18th November 2016. [check for an earlier answer]

answer, the government conceded that the current strength of drug inspectors was much below the 3200 required per Mashelkar's formula.²⁶ The three states with the highest number of sale/distribution outlets namely, Maharashtra (92359), Gujarat (39364) and Punjab (25917), have 161, 98 and 46 sanctioned positions for Drug Inspectors respectively. Per the Mashelkar formula, the required strength should have been 461, 196 and 129, respectively. Assuming each Drug Inspector can inspect 50 manufacturing units per year, Maharashtra, for example, with 3139 drug producing companies²⁷ would need 63 Inspectors for manufacturing licensees alone.

Our research shows that other SDRAs are in a similar position. The replies to our RTI applications regarding the sanctioned strength of Drug Inspectors when juxtaposed against the number of manufacturing units in the state helped derive the number of manufacturing units that each Drug Inspector is expected to inspect each year. This data shows the immense distance that remains to be covered.

The problem is compounded by the number of positions lying vacant. As per CDSCO's response to our RTI, of a sanctioned strength of 287 drugs inspectors at the central level, 64 positions are lying vacant. Similarly, at the level of DDC (I), of a sanctioned strength of 28 at the centre, 9 positions are lying vacant. In 2015, Chattisgarh reported approximately 700 pending license applications because the post of Deputy Drug Controller had been vacant for a year.²⁸ Himachal Pradesh reports a vacancy in 6 out of 22 sanctioned posts for Drug Inspectors.²⁹ Similarly, 13 out of 84 sanctioned posts in Jammu & Kashmir,³⁰ 15 out of 38 in Karnataka and 6 out of 23 in Tripura are reported vacant.³¹

²⁶ Lok Sabha Unstarred Question no. 4752 answered by the Minister of State in the Ministry of Health and Family Welfare on 23 March, 2018.

²⁷ Data from Lok Sabha unstarred Question 5761, dated 2 May 2013

²⁸ Jaiswal, A (2015), "With no Dy Drug Controller, over 700 drug license applications pending in Chhatisgarh", *Times of India*, 10 December, available at: <https://timesofindia.indiatimes.com/city/raipur/With-no-dy-drug-controller-over-700-drug-licence-applications-pending-in-Chhatisgarh/articleshow/50125538.cms>, last accessed 15 July 2019

²⁹ As of 24 December 2018, according to the website: <http://www.hp.gov.in/dhsrhp/drug%20inspector.pdf>

³⁰ As available at <https://dfcojk.org/details.php>

³¹ As available at <https://health.tripura.gov.in/drugregulation>

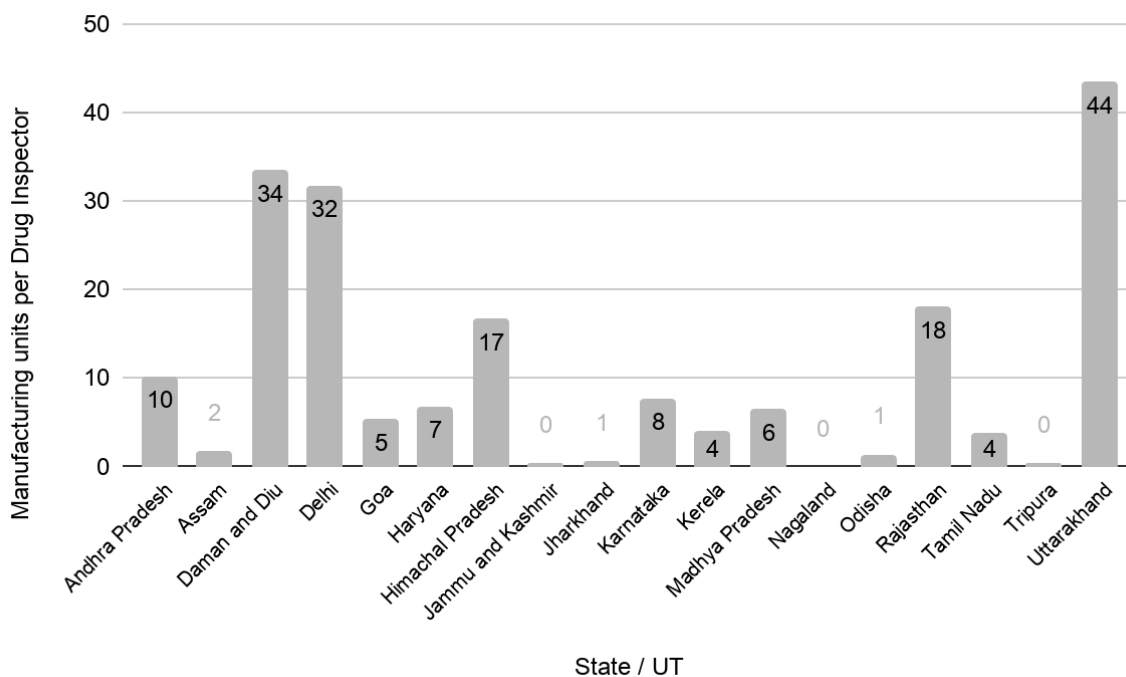


Figure 4: Manufacturing units per Drug Inspector
Source: RTI application responses; author compilation

B. Problem Identified: Inefficient Administration

Causes: Untrained And Unmotivated Regulators

Regular and updated training is essential to ensuring that a workforce remains ever ready to deal with new challenges, particularly in a field such as pharmaceutical regulation, where technology is changing at exponential speed.

However, in-field training processes in India appear to be limited at both the central and state levels. According to the Ministry of Health and Family Welfare, CDSCO, in recognition of its limitations in conducting Risk Based Inspection of pharmaceutical manufacturing units in the country, designed a special training programme for officers drawn from CDSCO, Drug Testing Laboratories and state Regulators. The trainees were subjected to assessment both before and after the training. A team of five officers each headed by a mid level officer was deputed to

carry out inspections of manufacturing units for a period of three days. At least five rounds of such inspections involving 136 units have been carried out so far.³²

Responses to pointed questions posed in RTI applications about the number and nature of training sessions conducted by CDSCO for in-house officers reveals that only eight training programmes have been conducted in the period between April 2015 and January 2019. Of these, half (4 training programmes) were clearly identified as induction training programmes for new recruits.

S No	Training Programme	Course duration	Participants
1	Training for drugs inspectors	One month	87 Drug Inspectors
2	Investigation techniques and launching of prosecution for drugs inspectors	3 weeks	57 Drug Inspectors
3	Good clinical practices	3 days	61 Drug Inspectors
4	Risk based inspection of manufacturing facilities	4 batches of 6 days each	240 Assistant Drug Controllers, Drug Inspectors, Assistant Drug Inspectors and Government Analysts

Table 2: Training programmes for officers other than new recruits (April 2015 to January 2019)

Source: RTI application responses from CDSCO; author compilation

Arguably, training programmes could be held more regularly and be tailored to respond on a needs-basis, depending on the skills and techniques that drugs controllers, drugs inspectors, and government analysts are likely to need on the field. The development of the training programme on risk-based inspection was a case in point of such responsive design. However, a one-time training programme is not likely to serve much purpose in ensuring the robust functioning of the regulatory machinery. Inspectors, analysts and other staff must be required to remain constantly updated with changing regulatory developments, scientific techniques, and investigation processes. These require different kinds of training toolkits and

³² Lok Sabha Unstarred Question no. 440 answered by the Minister of State in the Ministry of Health and Family Welfare on 16th December 2016.

methodologies and most importantly, constant updation. The data suggests that we are a long way off from imparting such training.

With respect to the qualifications for the post of Drug Inspector, the DTAB has recommended including Doctor of Pharmacy/Pharm.D and removing the proviso relating to experience under Rule 49 (i), (ii), and (iii).³³ Further, the Board also recommended that the minimum experience required for Licensing Authority relating to manufacturing and sale of drugs be raised to 10 years of regulatory experience instead of the existing 5 years.³⁴ The role of state drug inspectors regarding the regulation of food products is also contentious: it has been observed that other departments/organizations like the Food Safety and Standards Authority of India (FSSAI), Department of Pharmaceuticals, and departments dealing with cigarettes and other tobacco products continue to issue various notifications involving state Drugs Inspectors in additional activities like food regulation, pricing etc,³⁵ which directly impacts these officers in performing their duties with regard to drug regulation.

5. Infrastructure

A key indicator of the state of infrastructure in drug regulation would be the number of tests a laboratory is equipped to conduct compared with the actual number of tests that the laboratory conducts.

³³ DTAB meeting on 16 May 2018, Agenda No. 2.

³⁴ DTAB meeting on 12 February 2018, Agenda No. 8.

³⁵ DCC meeting on 9 June 2017

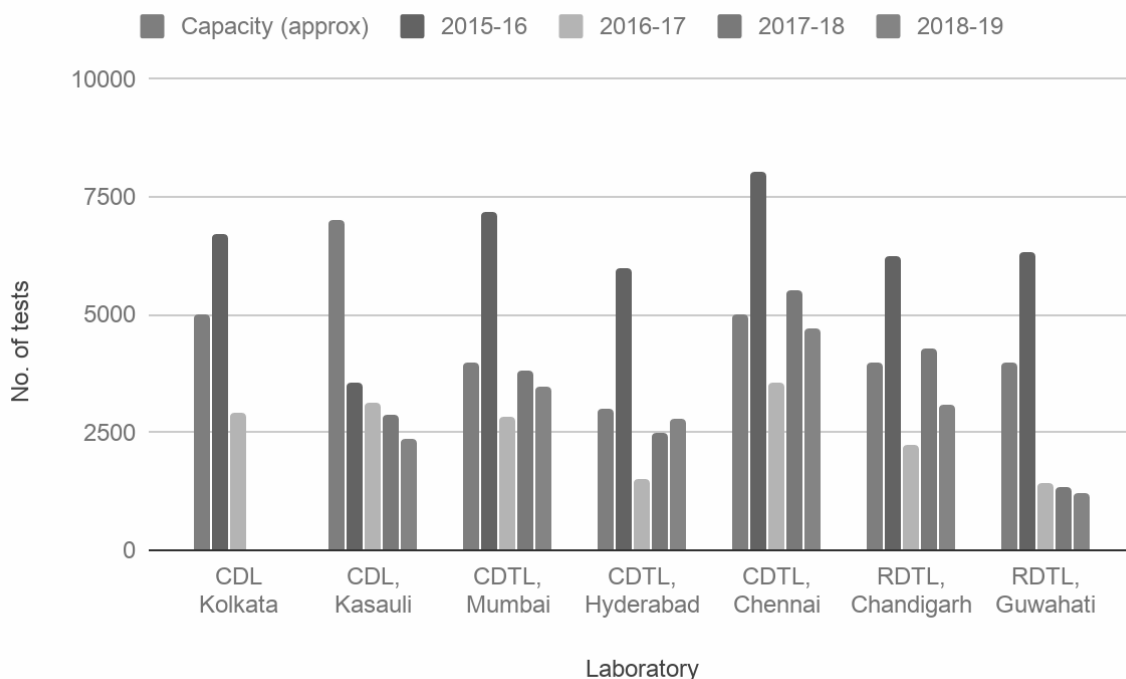


Figure 5: CDSCO testing capacity and actual testing undertaken (April 2015 - January 2019)

Source: Response to RTI applications from CDSCO; author compilation

According to the data, CDSCO laboratories generally remained underutilised for all years except 2015-16 (barring Chennai in 2017-18), when they were consistently over-used above capacity.

Of the SDRAs, there was a dearth of data provided in the RTI responses to enable the undertaking of any comprehensive comparative performance analysis, as only four states provided information on the capacity of laboratories within the state, and the number of samples actually tested. Nevertheless, based on the data provided, there is a clear case of underutilisation of the laboratories, with the exception of the state of Madhya Pradesh. It would appear that the laboratories are not being used to full capacity, with a state like Uttarakhand using less than 10 percent of its capacity in a given year.

State	Annual testing capacity	Total samples tested (1 April 2015- 31 Jan 2019)	Approximate samples tested per year (derived by authors)
Delhi	1850	2334	637
Jharkhand	500	885	241
Madhya Pradesh	1500	6433	1754
Uttarakhand	750	226	62

Table 3: Annual testing capacity and approximate samples actually tested per year in SDRAs

Source: RTI application responses; author compilation

In terms of digital infrastructure, the SDRAs appear to have taken steps towards reducing lags. Only 14 states make use of the XLN software for online submission and review of applications for grant of manufacturing and sale licenses. The states however also require physical submission of documents and fees, rendering the whole system an exercise in futility. Even though there was some improvement over the previous system, the current system suffers from some major flaws. Firstly, the records are non-porous. The data sets from one state do not interact with the data sets from another state. Secondly, there is no option to check the performance of the licensee over a period of time and/or across states. Thirdly, there is no option to check the progress of an inspection that is found to be non-compliant. The information gap highlighted previously also exists here. The system's failure to record convictions feeds into and compounds the information asymmetry already present in the system. It is worth noting that a proposal to develop a software for drug licensing management for all states has been fielded already, according to a DCC meeting.³⁶ The proposed cost of the project is 274.9 lakhs. The software is proposed to be launched within 45 days from the date of initiation and the project will be completed within a year. The total duration of the project is 3 years including 2 years maintenance period. It was pointed out that at present there is no custodian of the XLN software.³⁷ The most egregious report however seems to be regarding the

³⁶ DCC meeting 20 February 2019, Agenda No. 11

³⁷ DCC Meeting 4th and 5th November 2016

unavailability of physical infrastructure. Andhra Pradesh was reported as not having a permanent office.³⁸

Currently there are seven Central Drug Testing Laboratories at Kolkata, Chennai, Mumbai, Chandigarh, Hyderabad, Guwahati and Kasauli. In 2016, the government approved setting up of six more, but these are yet to materialise. State Drug Testing laboratories work alongside the enforcement wing of the SDRAs to regulate production and sale of drugs and cosmetics within the state. There are a total of 31 state drug testing laboratories, with 3 in Karnataka, 2 each in Kerala, Tamil Nadu and Maharashtra, 1 each at Goa, Himachal Pradesh, Andhra Pradesh, Gujarat, Rajasthan, Puducherry, Chhattisgarh, Punjab, Bihar, Odisha, Jharkhand, Jammu & Kashmir, Haryana, West Bengal, Telangana, Chandigarh, Uttar Pradesh, Delhi, Madhya Pradesh and Uttarakhand, Tripura, and Meghalaya.³⁹ There are no drug testing laboratories at Assam, Arunachal Pradesh, Mizoram, Manipur, Nagaland, Sikkim, Lakshadweep, Daman & Diu, and Dadra & Nagar Haveli who utilize the services of Regional Drug Testing Laboratories (Guwahati/Chandigarh), Central Drug Testing Laboratories (Mumbai/Chennai/Hyderabad) or Central Drug Laboratories (Kolkata/Kasauli) for drug testing.⁴⁰ The government had approved the setting up of six central drug testing laboratories and ten in the states/UTs.⁴¹ However, as of July 2019, there has been no addition to the list of functional drug testing laboratories.

As per the Lok Sabha answer by the Minister of Health and Family Welfare,⁴² the government intended to re-equip the drug testing laboratories with state of the art equipment, besides conducting training programmed for laboratory personnel of state and central laboratories to upgrade their analytical capabilities and skill sets. The scheme for strengthening the drug regulatory system was granted an outlay of

³⁸ DCC 29 September 2017

³⁹ Lok Sabha Starred Question no 54 answered by the Minister of Health and Family Welfare on 18th November 2016. [check for an earlier answer]

⁴⁰ Lok Sabha Unstarred Question No. 2262 answered by the Minister of Health and Family Welfare on 11 December 2015.

⁴¹ Lok Sabha Unstarred Question no. 3110 answered by the Minister of State in the Ministry of Health and Family Welfare on 5 January 2018.

⁴² Lok Sabha Starred Question no 54 answered by the Minister of Health and Family Welfare on 18 November 2016

Rs. 1750 Crore for 2015-16, 2016-17 and 2017-18.⁴³ Out of this, Rs. 900 crore was allotted to the central regulatory structure whereas the remaining Rs. 850 crore was approved as the central government's contribution for upgrading and strengthening the states' Drug Regulatory System. However, only 19 states submitted proposals for funds under the scheme.⁴⁴ The government approved the setting up of eight Mini Drug Testing Laboratories at Airports/Seaports in Ahmedabad, Bengaluru, Chennai, Kolkata, Delhi, Hyderabad and two at Mumbai out of which the labs at Ahmedabad Airport, Mumbai Airport, Mumbai Seaport and Bengaluru Airport are ready to be operational. As per a Lok Sabha answer, CDSCO has made arrangements for premises, major equipment and other infrastructure. The Deputy Drugs Controllers/Assistant Drugs Controllers of the concerned Zones/Sub-Zones were also authorized for procuring small equipment costing upto Rs. 3 lakh.⁴⁵

A. Problem Identified: Absent Or Inefficient Drug Labs

Causes: Lack Of Implementation; Lack of Regulation

Out of the 31 labs in various states, only 5 (from Maharashtra, Gujarat and Kerala) are NABL accredited. A sixth, from Karnataka, is in the process of accreditation.⁴⁶ The absence of NABL accreditation was discussed in a DCC meeting in October 2015 where it was decided that any state lacking the accreditation within two years may not be allowed to test thereafter.⁴⁷ The problem, however, sustains. Twelve states/UTs responded to our question about the annual drug testing capacity of their laboratories. Out of the twelve, only six states reported having a functioning state drug laboratory, with Tamil Nadu having two such labs.

⁴³ Lok Sabha Unstarred Question no. 640 answered by the Minister of Health and Family Welfare on 26 February 2016

⁴⁴ Lok Sabha Unstarred Question no. 2095 answered by the Minister of State in the Ministry of Health and Family Welfare on 29 July 2016.

⁴⁵ Lok Sabha Unstarred Question no. 4045 answered by the Minister of Health and Family Welfare on 10 August 2018.

⁴⁶ DCC meeting held on 20 February 2019, Agenda No. 19

⁴⁷ DCC Meeting held on 16 October 2015

State / UT	Testing Capacity	Samples collected per month per DI	Samples Tested (1 April 2015- 31 Jan 2019)	Pending (as of 31 Jan 2019)	Failed (1 April 2015- 31 Jan 2019)	Number of Labs
Andaman and Nicobar	0	No Limit				0
Arunachal Pradesh	0					0
Assam	0					0
Chattisgarh	500					1
Daman & Diu		No limit	124			
Delhi	1850	No Limit	2334	410	89	1
Gujarat		6	12029	3043	464	
Jammu and Kashmir		No limit/Depends on no of establishments	5918	18	100	
Jharkhand	500		885	318	25	1
Madhya Pradesh	1500		6433	1631	118	1
Mizoram	0	No Limit/Depends on funds	761		16	0
Nagaland	0	Min 25/year	170	43	7	0
Odisha		83	2166	706	95	
Sikkim	0					0
Tamil Nadu	10167	Min 7				2
Telangana		3	685		9	
Uttar Pradesh			182	57	0	
Uttarakhand	750		226	81	10	1

Table 4: Drug testing laboratories across India
Source: RTI application responses; author compilation

B. Problem Identified: Inefficient Drug Testing

Causes: Lack Of Adequate Budget, Trained Staff

In July 2018, the DCC recorded the inadequate state of funding, infrastructure and manpower in state laboratories.⁴⁸ SMPMA claimed that lack of proper equipment, inadequacy of reagents, improper storage conditions and absence of trained government analysts often contributed to a drug sample failing the tests. There is also no sanctioned strength for government analysts. Further, the DTAB rejected a proposal to amend qualification of government analysts.⁴⁹

It has been reported that there is often delay in releasing funds already issued to the SDRAs. The lack of adequate funding is not only because of unavailability of funds. According to DCC meeting minutes, states do not provide details of the usage of the grants already allotted or submit proposals and sign MOUs with the central government under the Scheme for Strengthening the State Regulatory System.⁵⁰ So far only 19 states have submitted proposals under the Scheme.

The central government plan to establish an academy for training drug regulatory officials from both enforcement and laboratory has also failed to the light of the day.⁵¹

6. Regulatory efficiency

The strongest indictment of the Indian pharma regulatory bodies comes from the increase in the number of drugs found not of standard quality (NSQ). In a nation-wide Drug Survey (2014-16) conducted to assess the extent of NSQ/Spurious drugs in the system, out of the 47,954 randomly drawn samples, 0.0245% were found to be spurious and 3.16% were found to be NSQ.⁵² As per the data from the RTI

⁴⁸ DCC Meeting held on 30 July 2018, Agenda No. 2

⁴⁹ DTAB meeting held on 16 February 2015, Agenda No. 11.

⁵⁰ DCC meeting held on 9 April 2018

⁵¹ DCC Meeting held on 16 October 2015

⁵² Lok Sabha Unstarred Question no. 239 answered by the Minister of State in the Ministry of Health and Family Welfare on 3rd February, 2017.

responses, approximately 7 in every 100 drug samples tested are found NSQ in Uttarakhand and Odisha. A Working Paper Series published in September 2014 reported that India supplied substandard medicines for markets with non-existent, under-developed or emerging regulatory oversight, notably Africa.⁵³ The government however, denounced the study for being misleading.⁵⁴ The Minister of Health and Family Welfare however added that the government was yet to decide on joining Pharmaceuticals Inspection Cooperation Scheme (PICS), a global regulatory body on drug inspections and manufacturing.

Year	Samples picked by CDSCO		Samples picked by SDRAs	
	Not of Standard Quality	Spurious/ adulterated	Not of Standard Quality	Spurious/ adulterated
2011-12	3.33	0.03	4.54	0.27
2012-13	2.8	Nil	4.03	0.11
2013-14	2.82	0.09	4.16	0.16
2014-15	3.35	Nil	4.98	0.11
2015-16	3.96	0.17	4.96	0.31

Table 5: Percentage of NSQ and Spurious drugs as identified by CDSCO and SDRAs

Source: Lok Sabha⁵⁵

The current strength of Drug Inspectors in the country is not adequate to enforce the DC Act mandate much less implement the recommendations of the Mashelkar Committee and the 59th Parliamentary Standing Committee reports. As per the XLN website (which only provides rankings for 14 states based on records of the last 6 months),⁵⁶ Delhi had 6147, Gujarat had 1467, Punjab had 1256, and Jharkhand had 1031 applications pending. The highest pendency percentage however belongs to Tripura and Chandigarh, 100% and 50% respectively, where the

⁵³ 'Poor Quality Drugs and Global Trade – A Pilot Study', Roger Bate, et all (National Bureau of Economic Research) – CHECK CITATION

⁵⁴ Lok Sabha Unstarred Question no. 1934 answered by the Minister of Health and Family Welfare on 31st July, 2015.

⁵⁵ Lok Sabha Unstarred Question no. 4595 answered by the Minister of Health and Family Welfare on 12th August, 2016.

⁵⁶See https://xlnindia.gov.in/FDCA_details_by_type.aspx.

SDRAs failed to dispose off the 4 applications each that they had received. On the other hand, Gujarat and Kerala top the list with 1% pendency.

State / UT	Total applications	Granted applications	Pending applications
Andaman and Nicobar	112	110	2
Daman and Diu	40	40	0
Gujarat	581	554	27
Jammu and Kashmir	4556	4556	NA
Jharkhand	1493	1477	0
Mizoram	2101	2101	NA
Nagaland	425	392	0
Odisha	4611	4192	1
Tamil Nadu	1131	1121	10
Telangana	2204	2204	NA
Uttarakhand	3307	3297	NA

Table 6: Applications received, granted and pending by various SDRAs as on 31 January 2019

Source: RTI application responses; author compilation

The response to RTI applications regarding the number of inspections conducted or drug samples collected was uneven, inconsistent and in most of the cases, avoided altogether. Only 9 states/UTs (Jammu and Kashmir, Jharkhand, Uttar Pradesh, Odisha, Mizoram, Telangana, Uttarakhand, Andaman and Nicobar and Daman and Diu) gave a number, in part or full, regarding the inspections conducted. When contrasted with the data available on the sanctioned strength of the respective departments, Jammu and Kashmir and Uttarakhand had the maximum workload, whereas Andaman and Nicobar and Odisha had the least. It must be noted that the DC Act and Rules mandate that every manufacturing premises be inspected 3 times and every retail establishment be inspected 2 times a year. Thus, the absence of an appropriate number of Drug Inspectors has not only created a significant pendency in application disposal but has also resulted in the drug manufacturing and retail establishments not being adequately inspected.

According to the replies received in response to our RTIs, 0 prosecutions were launched in Telangana for the 3853 premises found violating the conditions of their licence. However, 10 licences were cancelled and 710 were suspended as way of departmental action. Similarly, Jharkhand launched 7 prosecutions for the 1723 non-compliant licensees. Odisha launched 6 prosecutions for 876 non-compliances and Daman and Diu launched 0 for 19 non-compliances. Mizoram, on the other hand, initiated 4 prosecution proceedings and ordered 59 drug recalls out of the 141 reported violations. Jammu and Kashmir, Uttar Pradesh, Uttarakhand and Andaman and Nicobar reported zero cases of non-compliance.

State / UT	Total inspections	Non-compliant	Prosecutions
Jammu and Kashmir	27520	0	0
Jharkhand	8966	1723	7
Uttar Pradesh	907	0	0
Odisha	6260	876	6
Mizoram	1205	141	4
Telangana	16575	3853	0
Uttarakhand	1858	0	0
Andaman and Nicobar	120	0	0
Daman and Diu	407	19	0

*Table 7: Inspections and prosecutions by SDRAs
Source: RTI application responses; author compilation*

At the central level, the situation is similar with a large number of inspections launched, but a much smaller number of prosecutions launched, and practically none concluded. The data points to clear concerns about the capacity of Drug Inspectors to make the shift from inspection to prosecution, as well as capacity limitations with regard to pursuing cases to conclusion. The latter is also likely to be linked to larger problems of judicial capacity and legal advice available to the departments and authorities as well.

CDSCO Laboratory	Inspections	Prosecutions launched	Prosecutions concluded
Ahmedabad	1343	18	0
Bangalore	424	10	3
Chennai	1265	26	1
Ghaziabad	1407	35	0
Goa	131	7	0
Solan	1106	12	1
Hyderabad	1735	4	1
Indore	225	2	0
Jammu	104	3	0
Kolkata	640	16	0
Mumbai	1779	9	2

Table 8: CDSCO inspections and prosecutions (April 2015 - January 2019)

Source: RTI application responses; author compilation

Short-term regulation through piecemeal administrative action is an often criticized characteristic of the Indian drug regulators. Not only is the degree of penalty uneven across India, the absence of sustained risk-based regulation is evident from the skewed ratio between the number of licensees found non-compliant and the total number of prosecutions launched.

The DCC recommended setting up of an independent expert committee(s) to audit central and state drug regulatory authorities including laboratories.⁵⁷ The proposal is yet to pass the DTAB.

Currently, there is no system to ensure implementation of a recall order. To better implement the complete recovery of NSQ drugs from the market, the DCC has proposed allotting a dedicated Assistant Drug Controller to look after the implementation so as to ensure that every single unit of the defective drugs is recalled by the manufacturer from supply chain and a proper reconciliation of the

⁵⁷ DCC meeting 20 February 2019, Agenda No. 18

stocks of manufacture, distribution and recall is maintained.⁵⁸ Among other things, the DCC recommended:⁵⁹

1. In case of NSQ drugs, the manufacturers should be held responsible for recalling it from the supply chain voluntarily.
2. The manufacturers should have a system of regular market surveillance for monitoring of quality of the drugs placed in the market by drawing the sample from the supply chain and getting it tested to assess the quality and subsequent actions including recall of drug voluntarily in case it is found to be of NSQ.
3. The manufacturers should also have a system of recalling the drug voluntarily from the supply chain in case they find non-compliance/deficiencies in their manufacturing, quality control, out of specification observed in ongoing stability studies etc. through their internal audit.

During raids conducted by the CDSCO intelligence cell, a number of FDCs which were not approved by DCGI were found to be manufactured under the license granted by the state Licensing Authorities of Uttarakhand and Daman & Diu.⁶⁰ A proposal was advanced for creation of similar intelligence cells at the state level, which may be further integrated with the Central Intelligence Unit. The DCC recommended, that where a manufacturing unit has been banned or otherwise complained against by a foreign regulator/jurisdiction, states should conduct an inspection within 3 days and take immediate follow up action.⁶¹

7. Budget and financial administration

It is difficult to make any conclusive statements about the financial administration in drug regulation for the lack of definitive data from SDRAs. Even when combined with the publicly available data on SDRA budgets, the RTI

⁵⁸ DCC Meeting held on 30 July 2018, Agenda No. 2

⁵⁹ DCC Meeting held on 4th and 5th November, Agenda No. 11

⁶⁰ DCC Meeting held on 30 July 2018, Agenda NO. 8

⁶¹ DCC meeting held on 4th and 5th November 2016, Agenda No. 12